DT05 Rec'd PCT/PT0 2 2 DEC 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: MATSUI 9

In re Application of:
Hideki MATSUI et al.

Appln. No.: Not yet assigned

Filed: Even date herewith
For: INHIBITOR OF CONSTITUTIVE
ACTIVE FORMING OF CALCINEURIN

Atty. Docket: MATSUI 9

Conf. No.:

Art Unit:

Washington, D.C.

December 22, 2004

## INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office 2011 South Clark Place Customer Window, Mail Stop Amendment Crystal Plaza Two, Lobby, Room 1B03 Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §\$1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with 37 CFR \$1.97, as it is filed:
- [X] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [ ] B. before the mailing date of a first office action on the merits or before the mailing of a first Office

action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

- [X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:
- [] A. Document(s) \_\_\_\_\_\_ is/are deemed substantially cumulative to document(s) \_\_\_\_\_\_, and, in accordance with 37 CFR \$1.98(c), a copy of each of the former document(s) is not enclosed.
- [ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications) Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR \$1.98(d). Per 37 CFR \$1.98(d), copies of these documents need not be filed in this application.

- [X] 3. Documents  $\overline{AA}$  and  $\overline{AC}$  are not in the English language. In accordance with 37 CFR  $\S1.98(a)(3)$ , Applicant states:
  - [X] An English translation of document  $\overline{AA}$  (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.

- [ ] For documents \_\_\_\_\_\_, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.
- [X] A concise explanation of the relevance of document <u>AC</u> is found in the attached International Search Report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:
- [ ] A concise explanation of the relevance of document(s) \_\_\_\_ can be found on page(s) of the specification.
- [ ] A concise explanation of the relevance of document(s) \_\_\_\_ can be found on the attached sheet.
- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [ ] 5. Other information being provided for the examiner's consideration follows:
- 6. In accordance with 37 CFR §\$1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the

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face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK

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	(use as many sheets as necessary)			Examiner Name		
Sheet	1	of	2	Attorney Docket Number	MATSUI 9	

U.S. PATENT DOCUMENTS							
Examiner nitials*	Cite No.1	Document Number Number-Kind Code <sup>2 (III</sup> known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		US-					
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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*		Foreign Patent Number Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>3</sup> ( <i>if</i> known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>			
	AA	WO 02/00872 A2	01-03-2002	Exon-Hit Therapeutic SA.		ABS			

Examiner		Date		
Signature		Considered		

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. According to the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT			PLICANT	First Named Inventor	Hideki MATSUI	
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Sheet	2	of	2	Attorney Docket Number	MATSUI 9	

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Cite No.1							
АВ	Asai, A. et al., "High Level Calcineurin Activity Predisposes Neuronal Cells to Apoptosis", J. Biol. Chem., (1999), Vol. 274, No. 48, pp. 34450-34458.						
AC	Matsui, H. et al., "Saibo no Kino Seigyo to Calcium Seminar Calcineurin no Kozo to Kino", Clinical Calcium, (1993), Vol. 3, No. 11, pp. 58-63.						
AD	Kim, M. J. et al., "Calpain-dependent cleavage of cain/cabin1 activates calcineurin to mediate calcium-triggered cell death", Proc. Natl. Acad. Sci. USA, (July 2002), Vol. 99, No. 15, pp. 9870-5.						
AE	Morioka, M. et al., "Potential Role of Calcineurin for Brain Ischemia and Traumatic Injury", Prog. Neurobiol., (1999), Vol. 58, No. 1, pp. 1-30.						
AF	Springer, J. E. et al., "Calcineurin-Mediated BAD Dephosphorylation Activates the Capsase-3 Apoptotic Cascade in Traumatic Spinal Cord Injury, J. Neurosci., (2000), Vol. 20, No. 19, pp. 7246-51.						
AG	Tallant, E.A. et al., "Activation of a Calmodulin-Dependent Phosphatase by a Ca <sup>2+</sup> -Dependent Protease", Biochemistry, (1988), Vol. 27, No. 6, pp. 2205-11.						
	AC AD AE	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published  AB Asai, A. et al., "High Level Calcineurin Activity Predisposes Neuronal Cells to Apoptosis", J. Biol. Chem., (1999), Vol. 274, No. 48, pp. 34450-34458.  AC Matsui, H. et al., "Saibo no Kino Seigyo to Calcium Seminar Calcineurin no Kozo to Kino", Clinical Calcium, (1993), Vol. 3, No. 11, pp. 58-63.  AD Kim, M. J. et al., "Calpain-dependent cleavage of cain/cabin1 activates calcineurin to mediate calcium-triggered cell death", Proc. Natl. Acad. Sci. USA, (July 2002), Vol. 99, No. 15, pp. 9870-5.  AE Morioka, M. et al., "Potential Role of Calcineurin for Brain Ischemia and Traumatic Injury", Prog. Neurobiol., (1999), Vol. 58, No. 1, pp. 1-30.  AF Springer, J. E. et al., "Calcineurin-Mediated BAD Dephosphorylation Activates the Capsase-3 Apoptotic Cascade in Traumatic Spinal Cord Injury, J. Neurosci., (2000), Vol. 20, No. 19, pp. 7246-51.  AG Tallant, E.A. et al., "Activation of a Calmodulin-Dependent Phosphatase by a Ca²*-Dependent Protease",					

Examiner

Signature

Date

Considered

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.